UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

Plaintiffs,

v.

Defendants.

No. SA20CA0657 DAE

DEMAND FOR JURY TRIAL

FILED IN CAMERA/UNDER SEAL
PURSUANT TO 31 U.S.C. § 3730

RELATOR'S ORIGINAL COMPLAINT

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES and STATE OF TEXAS *ex rel.* CHRISTOPHER A. CAREW,

Plaintiffs,

v.

SENSEONICS HOLDINGS, INC. and SENSEONICS, INC.,

Defendants.

SA20CA0657DAE

No. _____

DEMAND FOR JURY TRIAL

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PURSUANT TO 31 U.S.C. § 3730

RELATOR'S ORIGINAL COMPLAINT

1. Christopher A. Carew ("Carew" or "Relator") brings this action against Defendants on behalf of the United States of America and the State of Texas through the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("False Claims Act" or "FCA"), and the Texas Medicaid Fraud Prevention Law, TEX. HUM. RES. CODE ANN. § 36.001, *et seq.* ("TMFPL"). Relator seeks to recover all available damages, penalties, and remedies against Defendants for Defendants' violations of federal and state law detailed herein.

INTRODUCTION

2. This is an action under the False Claims Act and the TMFPL to recover damages and civil penalties from Defendants for knowingly submitting, or causing to be submitted, false claims to government health care programs, including, but not limited to, Medicare, TRICARE, and Veterans Affairs health benefit programs, and for knowingly offering, paying, soliciting, and/or accepting remuneration in exchange for medical device referrals in violation of federal and state law.

3. From January 2019 to October 2019, Relator was employed as a Territory Manager for Defendant Senseonics, Inc. in the State of Texas. Senseonics, Inc. is a subsidiary of Senseonics Holdings, Inc., with both companies sharing a principal business address as well as common management and officers (both companies hereinafter collectively referred to as "Senseonics").

4. Senseonics hired Relator to manage sales of Senseonics' products and services in a large geographic area in Texas, including Austin, San Antonio, Corpus Christi, and other portions of South Texas. Senseonics directed Relator to report to Jeff Mountain, Senseonics' District Business Manager for Texas, Louisiana, Arkansas, and Oklahoma.

5. Senseonics tasked Relator with marketing its primary medical device—a blood glucose monitoring system for diabetic patients called the "Eversense Continuous Glucose Monitoring (CGM) System"—to endocrinologists and other physicians.

6. Senseonics refers to the Eversense CGM System as "the world's only long-term CGM system."[1] The system includes a sensor that is implanted under the skin, a removeable transmitter, and a software application for monitoring blood glucose levels. Senseonics markets the Eversense CGM System as a 90-day system. Every 90 days or so, a patient must visit his or her medical provider to have the implanted sensor removed and, if the patient chooses to continue using the product, have a new sensor inserted.

7. Facing considerable competition in the blood-monitoring and diabetic medical device markets, Senseonics set out to aggressively market the Eversense CGM System to patients and potential referral sources, including physician offices.

8. When Senseonics hired Relator, he had approximately 18 years of experience in medical-industry sales and marketing. During his relatively short time with Senseonics, Relator grew concerned about certain marketing and patient-solicitation practices employed by Senseonics.

9. Relator brings this action to stop Senseonics' abusive practices, to require Senseonics to reimburse taxpayers for false claims submitted to government payors, and to obtain appropriate penalties against Defendants as a result of those unlawful practices. The specific unlawful conduct at issue includes the following:

(i) Senseonics paid remuneration to, or on behalf of, important referral sources. Many of these referral sources were internally called "KOLs," which stood for "key opinion leaders." This remuneration included speaking fees, travel, meals, and procedure reimbursement

[1] Senseonics, *The Eversense CGM System*, https://www.eversensediabetes.com/eversense-cgm-

arrangements. One purpose of this remuneration was to obtain or maintain physician referrals for the Eversense CGM System. Senseonics also directed its sales personnel to handle protected health information of patients in order to secure sales of the Eversense CGM System. This sometimes resulted in Senseonics marketers providing free administrative labor to these physician practices when the physician's own employees were too busy, unable, or unwilling to submit patient information to distributors.

(ii) Senseonics solicited patients by paying remuneration to, or on behalf of, patients, including under the auspices of marketing survey reimbursements and device trade-in payments. Senseonics further solicited patients by paying for certain patient procedures.

(iii) Senseonics' marketing managers also directed its sales teams to solicit physicians to prescribe the Eversense CGM System by stressing the income stream the physician would enjoy as a result of patients returning every 90 days or so for a sensor removal and replacement. One Senseonics Regional Director overseeing the western portion of the entire United States directed his sales team to sell the patient stream as an "annuity" for doctors in order to solicit referrals for the device.

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system (last visited May 20, 2020).

10. Relator learned that at least one Senseonics representative was bringing patient files home from physician offices in order to procure sales. Senseonics expected its sales representatives to input patient protected health information (PHI) into a platform that could be accessed by distributors of the Eversense CGM System. Relator objected to these practices, and, soon thereafter, he was summarily fired.

PARTIES

Plaintiffs

11. Relator Christopher A. Carew is an individual citizen of the United States of America residing in Fair Oaks Ranch, Texas. He is a former employee of Senseonics and has direct, first-hand, and independent knowledge of conduct giving rise to this lawsuit. During the regular course of his employment, Relator had access to information as part of his job duties and responsibilities that supports the claims brought herein.

12. The United States of America is a Plaintiff and real party in interest as set forth in the False Claims Act. Relator seeks recovery on behalf of the United States for amounts paid by the United States Treasury, the Department of Health and Human Services, and any other government programs as a result of false claims submitted, or caused to be submitted, by Defendants, as well as all applicable enhancements and penalties.

13. The State of Texas is a Plaintiff and real party in interest as set forth under the TMFPL. Relator seeks recovery on behalf of the State of Texas as a result of false claims submitted, or caused to be submitted, by Defendants, as well as all applicable enhancements and penalties.

Defendants

14. Defendant Senseonics Holdings, Inc. is a Delaware corporation with a principal office located at 20451 Seneca Meadows Parkway, Germantown, Maryland 20876. Although Senseonics Holdings, Inc. is doing business in Texas, the Texas Secretary of State website appears to list no registered agent for the company. However, other public records list the company's registered agent as The Corporation Trust Company at 1209 Orange Street, Wilmington, Delaware 19801.

15. Defendant Senseonics, Inc. is a Delaware corporation with a principal office located at 20451 Seneca Meadows Parkway, Germantown, Maryland 20876. Although Senseonics, Inc. is doing business in Texas, the Texas Secretary of State website appears to list no registered agent for the company. However, other public records list the company's registered agent as The Corporation Trust Company at 1209 Orange Street, Wilmington, Delaware 19801.

RESPONDEAT SUPERIOR AND VICARIOUS LIABILITY

16. Defendant Senseonics Holdings, Inc. owns and/or controls Defendant Senseonics, Inc. and is vicariously liable for the actions and omissions of Senseonics, Inc. and its executives, employees, and agents. Defendants are each also vicariously liable for the actions and omissions of their executives, employees, and agents.

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction over these claims brought under the False Claims Act, 31 U.S.C. §§ 3279, *et seq.*, pursuant to 31 U.S.C. §§ 3730 and 3732, 28 U.S.C. § 1331, and 28 U.S.C. § 1345. This Court has supplemental jurisdiction

to entertain the Texas law causes of action under 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b).

18. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because that section of the False Claims Act authorizes nationwide service of process, implicating the National Contacts Test for personal jurisdiction, and because Defendants transact business in the Western District of Texas.

19. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1395(a) because Defendants transact business in this District.

20. There are no known public disclosures of the allegations and transactions contained herein that bar jurisdiction under 31 U.S.C. § 3730.

21. A copy of this Complaint is being served upon the Attorney General for the United States, the United States Attorney's Office for the Western District of Texas, and the Texas Office of the Attorney General. A written disclosure statement setting forth all material evidence and information Relator possesses is also being submitted to these offices as required by 31 U.S.C. § 3730(b)(2). *See* Fed. R. Civ. P. 4(d)(4).

22. Relator is the original source of the information forming the basis of this action because he possesses direct and independent knowledge of the non-public information upon which the allegations herein are based. *See* 31 U.S.C. § 3730(e)(4)(B). Relator acquired non-public information from approximately January 2019 to October 2019 that is independent from and materially adds to any publicly disclosed information relating to Defendants' violations of the False Claims Act and Texas law described herein. Relator's first-hand knowledge is derived from, among other things, internal emails,

reports, and correspondence, both verbal and written, with Defendants' employees and personnel.

23. Relator has complied with all conditions precedent to bringing this action.

LEGAL FRAMEWORK

A. The Medicare Program

24. In 1965, Congress enacted The Health Insurance Program for the Aged and Disabled through Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, ("Medicare"). Medicare is a federal health care program providing benefits to persons who are over the age of 65 and some under that age who are blind or disabled. Medicare is administered by the Centers for Medicare & Medicaid Services (CMS), a federal agency under the Department of Health and Human Services (HHS). Individuals who receive benefits under Medicare are referred to as Medicare "beneficiaries."

25. Medicare is a "Federal health care program," as defined in the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(f).

26. The Medicare Program includes various "Parts," which refer to the type of service or item covered. For purposes of this action, the primary component at issue is Part B. Medicare Part B covers, among other things, medically necessary outpatient care, physician services, and certain devices like the Eversense CGM System.

27. Medicare reimburses only reasonable and necessary medical products and services furnished to Medicare beneficiaries and excludes from payment services that are not reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.115(k).

Providers[2] must provide medical services to Medicare beneficiaries "economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a)(1).

28. Medicare utilizes "Medicare Administrative Contractors," sometimes referred to as "fiscal intermediaries" or "carriers," to administer Medicare in accordance with rules developed by CMS. These contractors are charged with and responsible for accepting Medicare claims, determining coverage, and making payments from the Medicare Trust Fund.

29. CMS hires these contractors to review, approve, and pay Medicare claims received from health care providers. Given that it is neither realistic nor feasible for CMS or its contractors to review all relevant medical documentation before paying each claim, payment is generally made under Medicare in reliance upon the provider's enrollment obligations as well as certifications on Medicare claim forms that services in question were "medically indicated and necessary for the health of the patient." In other words, Medicare and other federal health care programs are "trust-based" systems.

30. Medicare will only reimburse costs for medical services that are necessary for the prevention, diagnosis, or treatment of a specific illness or injury.

31. Certification attestations on Medicare enrollment forms, claim submissions, and Medicare Cost Reports play an important role in ensuring the integrity of the Medicare Program. *See* 42 C.F.R. § 413.24(f)(4)(iv).

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[2] Relator uses the term "providers" herein to include all health care practitioners, providers, and suppliers, notwithstanding definitional differences between "providers" and "suppliers" in some regulations.

32. Medicare enters into agreements with providers to establish their eligibility to participate in Medicare. Providers complete a Medicare Enrollment Application (often called a Form CMS-855A) whereby the providers must certify compliance with certain federal requirements, including specifically the Anti-Kickback Statute. Among other things, providers agree as follows:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction comply with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark Law), and on the provider's compliance with all applicable conditions of participation in Medicare.

Id. All providers participating in Medicare share these obligations.

33. The Medicare Enrollment Application also summarizes the False Claims Act in a separate section explaining the penalties for falsifying information in the application to "gain or maintain enrollment in the Medicare program." *Id.* § 14.

34. As further detailed below, Defendants unlawfully caused taxpayer funds to be paid from Medicare arising from violations of the Anti-Kickback Statute.

B. Veterans Affairs Health Benefit Programs and TRICARE

35. The Department of Veterans Affairs (VA) administers health benefit programs and pays for certain medical services. For instance, one of those programs is the Civil Health and Medical Program of the Department of Veterans Affairs, also known as "CHAMPVA," which provides health insurance coverage to dependents of veterans with disabilities or who are deceased.

36. TRICARE is a separate health benefit program administered by the Department of Defense, which covers certain military service members, military retirees, and families of service members and retirees.

37. TRICARE and VA health benefit programs such as CHAMPVA are "Federal health care programs," as defined in the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(f).

38. As further detailed below, Defendants unlawfully caused taxpayer funds to be paid from TRICARE and VA health benefit programs as a result of violations of the Anti-Kickback Statute.

C. Fraud and Abuse Statutes

39. According to the HHS-Office of the Inspector General ("HHS-OIG"), "[t]he five most important Federal fraud and abuse laws that apply to physicians are the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark law), the Exclusion Authorities, and the Civil Monetary Penalties Law (CMPL)."[3] At least two of these fundamental fraud and abuse laws, as well as the TMFPL, are at issue in this action.

(i) The False Claims Act

40. The False Claims Act imposes liability to the United States upon any individual who, or entity that, among other things, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or "knowingly makes, uses, or causes to be made or used, a false record or

statement material to a false or fraudulent claim," § 3729(a)(1)(B); or conspires to commit a violation of the False Claims Act, § 3729(a)(1)(C).

41. "Knowingly" is defined to include actual knowledge, reckless disregard, and deliberate ignorance. *Id.* § 3729(b)(1). The False Claims Act does not require proof of specific intent to defraud in order to establish a violation. *Id.*

42. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended, and 28 C.F.R. § 85.5, the applicable per-false-claim penalty under the False Claims Act assessed after January 29, 2018 is a minimum of $11,181 up to a maximum of $22,363.

(ii) **The Anti-Kickback Statute**

43. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), is a criminal statute that makes it illegal for individuals or entities to knowingly and willfully solicit or receive "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1).

44. The Anti-Kickback Statute also makes it illegal for individuals or entities to knowingly and willfully offer or pay "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or

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[3] HHS-OIG, *A Roadmap for New Physicians, Fraud & Abuse Laws*,

ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2).

45. The Anti-Kickback Statute further prohibits the solicitation, receipt, offer, and payment of any remuneration in exchange for referrals of individuals for services or items reimbursed in whole or in part by a Federal health care program. 42 U.S.C. § 1320a-7b(b). A "Federal health care program" includes any program providing health benefits that is funded directly, in whole or in part, by the United States, including, among others, Medicare, TRICARE, and VA health benefit programs. *See id.* § 1320a-7b(f).

46. The direct or indirect payment of remuneration to induce patient referrals for services reimbursed with federal health care funds constitutes illegal remuneration under the Anti-Kickback Statute. Violation of the Anti-Kickback Statute is a felony punishable by fines and imprisonment. 42 U.S.C. § 1320a-7b(b)(2).

47. The Anti-Kickback Statute arose out of Congress's concern that health care decisions would be inappropriately induced through the payment of remuneration (*i.e.*, things of value), which would undermine the goals of ensuring fair competition for federal funds and providing the highest quality of health care to patients in a market driven by quality of care, not financial incentives. To protect federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. Congress has strengthened the Anti-Kickback Statute on multiple occasions since its enactment to ensure that kickbacks masquerading as legitimate transactions do not evade the statute's reach.

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https://oig.hhs.gov/compliance/physician-education/01laws.asp (last visited May 20, 2020).

48. As amended by the Patient Protection and Affordable Care Act of 2010 ("ACA"), Pub. L. No. 111-148, § 6402(f), the Anti-Kickback Statute provides that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g). According to the ACA's legislative history, this amendment to the Anti-Kickback Statute was intended to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854. In other words, compliance with the Anti-Kickback Statute is material to the government's payment decisions.

49. HHS-OIG has promulgated "safe harbor" regulations that identify payment practices that are not subject to the Anti-Kickback Statute because such practices are unlikely to result in fraud or abuse. *See* 42 C.F.R. § 1001.952. Safe harbor protection is afforded only to those arrangements that meet all of the specific conditions set forth in the safe harbor. Defendants' conduct forming the basis of this action does not enjoy the protection of any safe harbor.

50. Compliance with the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), is a condition of payment under federal health care programs, and providers participating in federal health care programs must agree to comply with the Anti-Kickback Statute and certify such compliance.

(iii) **Texas Law**

51. Texas law also applies to the conduct at issue by Defendants detailed in this action.

52. As defined above, Texas Medicaid Fraud Prevention Law, TEX. HUM. RES. CODE ANN. § 36.001, *et seq.* ("TMFPL"), the Texas Human Resource Code – Medical Assistance Program, TEX. HUM. RES. CODE ANN. § 32.039(b) ("MAP"), and the Texas Patient Solicitation Act, TEX. OCC. CODE ANN. § 102.001, *et seq*, ("TPSA") apply to certain conduct pertaining to the solicitation of patients.

53. Section 36.101 of the TMFPL authorizes a private right of action for violations of Section 36.002, and Section 36.110 establishes a right to an award to the private plaintiff.

54. TMFPL § 36.002(13) prohibits a person from knowingly engaging in conduct that constitutes a violation under Section 32.039(b) of the Texas Human Resources Code, Chapter 32 – Medical Assistance Program (MAP). MAP § 32.039, entitled "DAMAGES AND PENALTIES," contains a series of enumerated violations, including prohibitions that closely mirror the prohibitions contained in the Anti-Kickback Statute. *See* MAP § 32.039(b)(1-b) – (1-f).

55. However, not all actionable violations require any connection to Texas Medicaid. In particular, MAP § 32.039(b)(1-a) makes it a violation for any person to engage in conduct that violates Section 102.001 of the Texas Occupations Code—the TPSA referenced above.

56. Section 102.001 of the TPSA, entitled "SOLICITING PATIENTS; OFFENSE," provides in relevant part that a "person commits an offense if the person knowingly offers to pay or agrees to accept, directly or indirectly, overtly or covertly any remuneration in cash or in kind to or from another for securing or soliciting a patient or patronage for or from a person licensed, certified, or registered by a state health care regulatory agency." Like the Anti-Kickback Statute, it is a crime to violate the TPSA. Importantly, the TPSA does not tie the unlawful conduct to reimbursement by any federal or state health care programs—penalties under the TMFPL are recoverable for violations of the TPSA regardless of the payor involved.

57. Under Section 36.052 of the TMFPL, a person committing an unlawful act is liable for, among other things, a civil penalty tied to the False Claims Act. TMFPL §§ 36.052(1)–(4). The applicable per-unlawful-act penalty under the TMFPL assessed after January 29, 2018 is a minimum of $11,181 up to a maximum of $22,363, per defendant. *Id.* § 36.052(3)(B); 28 C.F.R. § 85.5.

58. Section 36.110 of the TMFPL entitles a private plaintiff to recover up to 30 percent of the amounts recovered in the action.

DEFENDANTS' UNLAWFUL CONDUCT

59. Relator sets forth and details the unlawful conduct forming the basis of this action by category of conduct. Relator discovered information and evidence supporting these allegations during his time dealing with and working for Senseonics.

A. Senseonics paid remuneration to, or on behalf of, physicians in order to obtain or maintain referrals for the Eversense CGM System.

60. Based on Senseonics' news releases, from 2011 through approximately 2017, the company was raising money, arranging distribution channels, testing the Eversense CGM System, and planning to take Senseonics' Holdings, Inc. public.

61. On June 21, 2018, Senseonics announced that the United States Food and Drug Administration ("FDA") had approved its Premarket Approval application to market the Eversense CGM System for monitoring blood glucose levels. The FDA approved the device as "adjunctive," meaning it could "complement, not replace, information obtained from standard home blood glucose monitoring devices."[4]

62. Senseonics then set out to build a market for its device, which included a national marketing strategy to induce endocrinologists and other physicians to prescribe the device for diabetic patients.

63. Senseonics hired Relator as part of this marketing effort. Relator learned about a sales position with Senseonics through a recruiter. Relator had a phone interview with John Ramirez, Senseonics' Regional Director for the western portion of the United States. A few days later, Senseonics flew Relator to Washington, D.C. for interviews with John Ramirez and Rudy Thoms, Senseonics' Head of Sales in the United States. A few days after that, Relator interviewed with Jeff Mountain, Senseonics' District Business Manager for Texas, Louisiana, Arkansas, and Oklahoma. Relator was subsequently offered a job.

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[4] *See* U.S. Food & Drug Administration, *Premarket Approval (PMA)*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160048 (June 21, 2018).

64. A letter from Senseonics dated January 11, 2019, confirmed Relator's offer of employment and explained that his duties would include managing sales "directly to end-users of the organization's products or services in a large specified geographic area." The letter also informed Relator that he would report to Jeff Mountain or his designee.

65. Relator learned that his job would require him to visit physician offices and market the benefits of the Eversense CGM System directly to physicians and their staff. Relator also discovered that Senseonics had set aggressive sales quotas for him and other sales representatives.

66. In February and March of 2019, Relator attended various trainings related to diabetes, the Eversense CGM System, the sensor implantation procedure, and reimbursement for the device, as well as expectations for collecting personal and medical information on potential patients.

67. In early February 2019, Relator introduced himself to a physician in Austin, Texas who was already on Senseonics' radar as a referral source, referred to herein as "Dr. B." Senseonics personnel referred to Dr. B as a "key opinion leader," or "KOL." Dr. B had just returned from a weekend in Las Vegas at a Senseonics-sponsored event where he had apparently been scheduled to speak for Senseonics on multiple topics, including under the topic heading "Welcome – Senseonics Mission/Vision."

68. Relator soon learned that Dr. B was an important account for Senseonics. In fact, in an email dated May 16, 2019, Senseonics Senior Director of Reimbursement and Market Access, Chip Moebus, wrote Rudy Thoms and John Ramirez explaining that he was doing his best "to give Dr. [B] the 'white glove' treatment."

69. On May 23, 2019, John Ramirez instructed Senseonics' "Accounts Payable" to reimburse Dr. B for three patients who had apparently needed early replacements of their Eversense CGM System sensors. A Senseonics staff accountant replied to Mr. Ramirez, "None of these three contract (sic) has been signed by Senseonics. Could you please get them signed and approve a payment of $1,200.00 to [Dr. B]?"

70. The three contracts referenced by the Senseonics accountant appear to have been "Sensor Procedure Agreement[s]" entered into between Senseonics and Dr. B in or around May 2019. According to the agreements, Senseonics agreed to pay $400 to Dr. B for each "Sensor Removal & New Sensor Implantation."

71. In an email to Mr. Ramirez dated June 5, 2019, the same Senseonics accountant confirmed that Senseonics had paid Dr. B "$1,200.00 through CK# 17362." According to the email, Dr. B's practice then asked that the check be made out to the practice, not Dr. B individually.

72. These apparent payments to Dr. B or his practice are problematic, and Senseonics' own documents explain why. First, in or around August 2019, Senseonics unveiled a new program called the "Certified Eversense Specialist Network & Support Program" (the "CES Program"). Under the CES Program, Senseonics would pay doctors to perform the insertion of the Eversense CGM Sensor. According to internal slides, Senseonics directed its sales teams to "[t]arget Strategic locations around high volume accounts[.]" Under the CES Program, these so-called CES Specialists could not have the ability to "prescribe, influence or direct a patient to Eversense." An internal slide for

Senseonics' sales teams included the following proposed explanation for prescribing physician about the CES Program:

- Of course, we cannot reimburse an HCP that has the ability to prescribe, influence or direct a patient to Eversense. This would be considered inducement and a violation of the anti-kick back statute. Of course we **would never** put your reputation or practice at risk. So we created this program as a means for you to refer out the procedure when necessary, and of course you can continue to do your own procedures.

Notwithstanding actual knowledge of the Anti-Kickback Statute and the recognition of prohibitions on paying inducements to physicians who prescribe the Eversense CGM System, Senseonics had nonetheless arranged to pay Dr. B—one of its "KOLs"—or his practice for performing insertions.

73. In addition, the amounts Senseonics arranged to pay Dr. B or his practice were also problematic according to what Senseonics was telling its own employees. As further discussed below, John Ramirez directed his sales teams to encourage physicians to set insertion or removal/insertion charges around $200 to $250 to keep patients coming back. In a May 12, 2019 email entitled "Talk business to business- [Dr. B]-internal only[,]" Mr. Ramirez wrote the following:

Team,

Let's get him to think about "right now". Most of the insurers are not covering Eversense, get your physicians to think about:

- **Patient numbers- this is an annuity – offices need patients coming back...over and over again**
  - **Need a low insertion and removal price**
  - **Charge $400 -$500 = very few patients will come back**
  - **Why not just set your fee schedule at $200 insertion and $250 insertion/removal until January**
- **How much time are they really spending in the room w/ the patient?**
  - **$500 for 15 minutes will not hold up**
  - **There are no other codes that pay this**
- **Not the only game in town- Doctor- if you charge $400, patients who want Eversense will shop around**

Mr. Ramirez reiterated this message in an internal sales team call on May 29, 2019, presenting a "messaging" slide that stated in part: "15 minute procedure = $500 is not reasonable (no procedure pays this amount)."

74. Mr. Ramirez directed his sales teams to tell physicians to set fee schedules around $200 to $250, saying "$500 for 15 minutes will not hold up" and "if you charge $400, patients who want Eversense will shop around[.]" In other words, $400 was not a reasonable charge that the market would accept for performance of these medical services, yet Senseonics nonetheless agreed to pay Dr. B—a major referral source and "KOL"—$400 per removal/insertion for the relevant patients.

75. Relator learned that Senseonics had identified another "KOL" in his territory, a physician practicing near San Antonio, referred to herein as "Dr. W." Dr. W was also an important account for the company. In an email dated April 5, 2019, John Ramirez checked in on Dr. W's account, stating, "We flew her to Chicago to speak for us a while back = KOL. What is her status on REQs, Bridge and a prompt pay price?"

76. Jeff Mountain wrote in an email that same day that Dr. W was "an important KOL in TX and nationally." Mr. Mountain added John Ramirez and Rudy Thoms to the email, writing, "I am copying you in on this as I know this was an account of particular strategic interest[.]" Mr. Thoms responded, "Great to hear. Let's get [Dr. W] back engaged again. I am happy to go out to dinner with her in the coming months as she was an early adopter that fell off the radar dramatically."

77. These so-called "KOLs" were key referral sources for Senseonics. In fact, in an email dated February 26, 2019, Senseonics' Government Account Manager in the US

Region, Mike Zumdahl, emailed Jeff Mountain, among others, explaining he wanted to target two different clinics in Mr. Mountain's area. Mr. Zumdahl explained, "San Antonio is a hot bed for VA & TRICARE patients, so it's critical that we get in front of the key opinion leaders in this market." This shows that Senseonics believed these "KOLs" could help bolster Senseonics' access to government-payor patients, and they cultivated these relationships in order to influence referrals for those patients.

78. Relator soon had pressure from both his boss, Jeff Mountain, and his boss' boss, John Ramirez, to grow sales quickly. They reminded Relator that he had been assigned to a territory already containing multiple "key opinion leaders," or "KOLs."

79. As suggested above, Senseonics used dinners with physicians to drive referrals. On April 11, 2019, John Ramirez wrote his sales team for the West Region attaching a list of planned attendees at "AACE."[5] Mr. Ramirez instructed his team to "identify targets" for dinner, particularly "current prescribers, but other big potential prescribers will be considered."

80. Mr. Ramirez followed up on this message six days later with the following email mentioning "high potential clinicians" and "high value targets":

[5] This acronym apparently stands for "American Association of Clinical Endocrinologists." The organization held a conference in Los Angeles in April 2019.

From:	John Ramirez
Sent:	Wednesday, April 17, 2019 10:33 AM CDT
To:	West Region Sales
CC:	Melissa Coleman
Subject:	AACE Dinners are open all high potential clinicians-
Attachments:	Fwd AACE Attendee List and Pre-Show Email.msg.eml, AACE Dinner Meeting Flyer -Thursday Friday.pdf

Team,

I have asked the DBMs to make filling these dinners this a priority! Having said this, we want high value targets that you have already met with and you feel with embrace Eversense. Please work with your DBMs to pump up these events.

Thanks,

John Ramirez
Director- Western Area

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81. On or around April 30, 2019, an individual named "John" (believed to be John Ramirez) prepared an email explaining, "We just attended the AACE meeting in LA and one of our KOLs was less than positive. We cannot have this happen again[.]" The email continued, "[Dr. B] will be a key speaker at the ADA in early June. We have 5 weeks to prepare him." Senseonics sales representatives were instructed to be in a

position to answer key questions, including "What will [Dr. B] say on the podium and how can we be sure it will be absolutely positive?"

82. John Ramirez wrote Relator an email on June 30, 2019, copying Jeff Mountain, in which he explained that he was "excited to see [Relator's] progress at reviving the KOLs in [his] territory, while developing the new ones." Mr. Ramirez stressed certain sales tactics, including proposing "education nights" for an important clinic and nurse practitioner named "Joe." For these so-called "education nights," Mr. Ramirez explained that Senseonics could advertise in the paper, offer food and drinks, get patient paperwork signed (including certificates of medical need) "on the spot," and hopefully "groom Joe for future speaking engagements." Less than a week prior, Mr. Ramirez arranged for a dinner with Joe and Relator at a steakhouse, and Mr. Ramirez invited Ed Monas, Senseonics' Director of Commercial Operations.

83. Mr. Ramirez's June 30, 2019, email also stressed Dr. B's "importance to Senseonics," explaining that "we have paid him to speak at multiple meetings."

84. Jeff Mountain replied to Mr. Ramirez and Relator on July 1, 2019, explaining that Relator had "more KOL's (sic) already prescribing than anyone in the U.S. so we are expecting big things of you." Mr. Mountain continued, telling Relator that he "should be living in these accounts" and explaining that it "truly goes a long way and puts Eversense on their mind for every patient needing a CGM."

85. Senseonics also instructed its sales personnel to enter protected health information of patients for physicians' offices in order to secure sales of the Eversense CGM System. This resulted in Senseonics marketers providing free labor to these

physician practices when the physician's own employees were too busy, unable, or unwilling to submit patient information to distributors.

86. An example of this conduct can be seen in a second-quarter "District Presentation" presented by Jeff Mountain. In his presentation, Mr. Mountain provides an overview of various territories in his district, highlighting the status of certain "Focus Accounts." For one "account," Mr. Mountain wrote that the doctor was "very unorganized" and his staff was "not good with paperwork." Mr. Mountain instructed his team that they "[n]eed to utilized (sic) Stacy in this office." Mr. Mountain was apparently referring to a Senseonics representative named Stacy Garza.

87. In the same presentation addressing a separate physician's office in San Antonio, Mr. Mountain wrote that this "will take a lot of time and hand holding for paperwork." His next point read, "Utilize Stacy in this account[.]" Thus, Senseonics effectively provided free administrative labor to physicians that were in position to make patient referrals and that Senseonics was actively soliciting for such referrals.

88. Relator recalls Stacy Garza handling paperwork for various physician offices. Relator also recalls Ms. Garza informing him that she was taking patient files home to enter information into a portal to be accessed by distributors. Relator objected to this practice, which ultimately led to his firing.

B. Senseonics paid remuneration to patients in order to obtain or maintain sales of the Eversense CGM System.

89. On January 30, 2019, just after Relator began his employment with Senseonics, a Senseonics District Clinical Manager named Brenda McGuire forwarded him an email with what she called "Background info." The forwarded email chain was

between an endocrinology office in Austin, Texas, and another Senseonics employee named Dan Daniels.

90. In a November 26, 2018 email, Mr. Daniels wrote to a representative of the Austin clinic explaining the importance of inputting patients into a portal to help with obtaining insurance coverage and "eventually Medicare." Mr. Daniels went on to explain the following about Senseonics' "patient marketing" efforts:

> In regards to the patient marketing to help offset some of the copays, yes, I don't have the details yet, but my understanding, it will be a series of marketing surveys, (sic) that the patient will fill out that will track their Eversense experience.

As it turns out, Senseonics did unveil a so-called "Market Research Survey Program," offering eligible patients up to $400 for participating in a series of online surveys. As Mr. Daniels' email explained, the program was passed off as "research," but it was actually designed to solicit patients by offering them remuneration.

91. In or around March 2019, Senseonics unveiled its "Eversense Bridge Program." Senseonics offered this program to certain commercially insured patients, marketing it as an opportunity for "eligible patients to get Eversense products for just $99 out of pocket costs . . . regardless of deductible or copay."

92. In addition, under its CES Program, Senseonics agreed to pay for the entire cost of a patient's insertion and/or removal if the patient's insurance did not pay for it.

93. Further, Senseonics offered a "trade-in" program under which it would pay eligible commercial patients up to $500 for trading in competitor products even though these products had little to no resale value in the marketplace.

94. These offers and payments of remuneration to patients were designed to bolster Senseonics' patient base for its Eversense CGM System by inducing patients to purchase the system when they otherwise would not have been willing to pay the high upfront costs for the system. Once these patients were "locked in" to the Eversense CGM System, according to Senseonics' sales managers, they would become an "annuity" for friendly referring physicians that Senseonics had "groomed," with "locked in" patients returning every 90 days or so for another procedure and another payment to the prescribing physician and/or the physician performing the procedure.

C. Senseonics instructed its sales teams to solicit physician referrals by stressing the income stream the physicians could enjoy with patients returning every three months.

95. As discussed above, on May 12, 2019, John Ramirez wrote an internal email entitled "Talk business to business- [Dr. B]-internal only." In it, Mr. Ramirez instructed his team to "get your physicians to think about" certain items. First, on the list: "**Patient numbers- this is an annuity – offices need patients coming back…over and over again**[.]" (emphasis added). Mr. Ramirez continued, explaining that physicians needed "a low insertion and removal price" to keep patients coming back. He wrote, "Why not just set your fee schedule at $200 insertion and $250 insertion/removal until January[?]"

96. As described above, this message was reinforced by Mr. Ramirez in slides dated May 29, 2019, entitled "Western Regional Good News Call." In a slide aimed at "messaging," Senseonics stressed that its sales teams should message to physicians getting

patients "locked in" by setting lower procedure fees to drive larger volume. The relevant section of the slide read as follows:

- **Does your physician want his patients locked in**
- **Economy of Scale- Does the physician want to do 4 a year or 100 a year?**
  - **4 x $500 = $2000 Vs. 100 x $200 = $20,000**
- **15 minute procedure = $500 is not reasonable (no procedure pays this amount)**
- **Patients will shop around**

97. In other words, Senseonics was instructing its sales representatives to encourage physician referrals of the Eversense CGM System by selling doctors on how much money they could make off their patients returning every 90 days or so and paying to undergo a medical procedure: the so-called "annuity." Then, to help maintain the "annuity," sales representatives were to help physicians set a fee schedule that would incentivize physicians to prescribe the Eversense CGM System, but not be so expensive as to discourage patients from coming back.

98. To help solidify this "annuity," Senseonics paid remuneration to patients as an inducement to help get them in the doors of referring physicians and "KOLs."

D. Senseonics targeted government-payor patients.

99. Senseonics targeted TRICARE and VA health benefit program patients around the country.

100. On February 13, 2019, Senseonics' Government Account Manager for the US Region, Mike Zumdahl, sent an email explaining that the company was targeting TRICARE and VA accounts. Mr. Zumdahl explained, "Use the attached Jun'18 VA insulin report to help with targeting, but I've also included the top 20 Dexcom VA accounts below – **these are the VA's** [sic] **we must attack first!**" (emphasis in original).

101. Senseonics estimated that the cost to the government for an Eversense CGM System for each VA patient was approximately $5,400 a year.

102. On February 18, 2019, Mr. Zumdahl widely circulated an internal email that attached a VA memorandum explaining the "criteria for identifying Veterans who may be appropriate candidates for the use of Continuous Glucose Monitoring Devices (CGM)." The memorandum listed specific "Criteria for Issuance" that had to be met before a physician prescribes the device as well as what must be documented in the veteran's medical record. However, in capitalized, bold, red letters, Mr. Zumdahl instructed Senseonics employees as follows: "**DO NOT LEAVE BEHIND OR E-MAIL TO CUSTOMERS**[.]" Later in the same email, he reiterated: "**DO NOT PRINT OFF, LEAVE BEHIND, OR E-MAIL**[.]"

103. It is concerning that Senseonic's Government Account Manager did not want physicians to have a copy of a VA document detailing the requirements that must be met before providers could prescribe CGM devices to veterans and before the taxpayers would pay for the device. Without specific criteria to guide them, providers may have over-utilized the Eversense CGM System for VA health benefit program patients, which of course would financially benefit Senseonics.

104. On September 20, 2019, Mr. Zumdahl sent an email explaining that there were "already hundreds of TRICARE patients all over the country experiencing the benefits of Eversense." TRICARE reimburses for "Continuous Glucose Monitoring System Devices," with applicable HPCPS Codes of A9276 – A9278, K0553, K0554,

S1030, S1031 and corresponding CPT procedure codes of 95250, 95251, 0446T – 0448T.

105. As described above, in an email dated February 26, 2019, Mr. Zumdahl wrote Jeff Mountain and others seeking to set up appointments in San Antonio because it "is a hot bed for VA & TRICARE patients." In fact, internal Senseonics documents suggest that the company targeted VA health benefit patients and VA facilities all across the country. One document indicates that the company planned to "target" the country's largest VA medical center endocrinologists using VA insulin data, which included the following areas: Cleveland, North Florida/Southern Georgia, Dallas, Houston, Orlando, and Atlanta.

106. On June 6, 2019, the FDA approved the Eversense CGM System for therapeutic dosing (non-adjunctive use). The following day, Mike Zumdahl sent an email to multiple recipients stating that "this label update will allow us to start working with Medicare for coverage of Eversense for Seniors."

107. On November 12, 2019, Senseonics announced that CMS had finalized a "national payment rate for Eversense" and that the Eversense CGM System would "be reimbursed through the Part B Medical Services benefit for Medicare beneficiaries."[6]

108. Through the tactics and inducements described above, Senseonics built a base of referring physicians with "locked in" patients financially benefitting referring physicians. In addition to targeting TRICARE and VA health benefit program patients,

[6] *See* Senseonics Investor Relations, *Medicare Establishes National Payment Rate for Eversense CGM® System*, https://www.senseonics.com/investor-relations/news-releases/2019/11-12-2019-210212686 (Nov. 12, 2019).

Senseonics had established, largely through various forms of patient and physician inducements, a referral network that it could then rely on once CMS approved payment for the Eversense CGM System.

CONCLUSION

109. Medical patients are not annuities. As the Department of Justice has stated over and over again, prescription and treatment decisions should not be based on financial arrangements, and medical device companies should not be involved in treatment decisions.[7] Failure to comply with federal law governing these decisions results in false claims when they are submitted to federal payors. And, under Texas law, each time Senseonics helped arranged for remuneration to flow to patients or providers for the purpose of soliciting referrals, regardless of payor, constitutes an unlawful act.

110. The above provides an inside look at how Senseonics has infiltrated physician offices and corrupted medical decision-making in order to change referral patterns through incentives and patient solicitation. These unlawful acts paved the way for Senseonics to profit unjustifiably at the expense of taxpayers and patients. These unlawful activities must be stopped and remedied.

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[7] *See* United States Department of Justice, *Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay $125 Million to Resolve Criminal Liability and False Claims Act Allegations*, https://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million (Oct. 29, 2015) ("The Justice Department is committed to protecting the integrity of physician prescribing decisions and ensuring that financial arrangements in the healthcare marketplace comply with the law. The Department will continue

CAUSES OF ACTION

FIRST CLAIM FOR RELIEF

Violations of the False Claims Act: False Claims for Payment
31 U.S.C. § 3729(a)(1)(A)

111. Relator realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this claim for relief.

112. Through the acts and omissions alleged above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the United States for payment or approval within the meaning of 31 U.S.C. § 3729(a)(1)(A).

113. Defendants violated the federal False Claims Act by submitting, or causing to be submitted, claims for reimbursement from federal health care programs, including TRICARE, VA health benefit programs, and Medicare knowing that those claims were ineligible for the payments demanded.

114. False claims submitted, or caused to be submitted, by Defendants included claims tainted by Anti-Kickback violations.

115. Each claim submitted as a result of the Defendants' illegal conduct represents a false claim.

116. The United States, unaware of their falsity, paid and may continue to pay claims that would not be paid but for Defendants' unlawful conduct.

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to hold companies and responsible individuals accountable when they use improper incentives, like those alleged here, to promote their products.").

117. Defendants' conduct described herein was knowing, as that term is used in the False Claims Act, and material, as that term is defined in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

118. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

SECOND CLAIM FOR RELIEF

Violations of the False Claims Act: Use of False Statements
31 U.S.C. § 3729(a)(1)(B)

119. Relator realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this claim for relief.

120. Defendants knowingly used or caused to be made or used false records or statements that were material to false or fraudulent claims for payment submitted to federal health care programs. Those false records or statements used or caused to be used by Defendants include false certifications of compliance with the Anti-Kickback Statute.

121. Defendants' conduct described herein was knowing, as that term is used in the False Claims Act, and material, as that term is defined in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

122. The United States, unaware of the falsity of the records and statements made by, used, or caused to be used by Defendants, approved, paid, and participated in payments made by federal health care programs for claims that would otherwise not have been approved and paid.

123. By reason of these false records or statements, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

THIRD CLAIM FOR RELIEF

Violations of the False Claims Act: Conspiracy to Violate the False Claims Act
31 U.S.C. § 3729(a)(1)(C)

124. Relator realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this claim for relief.

125. Defendants knowingly conspired with each other and/or other individuals and agents to violate 31 U.S.C. §§ 3729(a)(1)(A) and (B) and to defraud the United States by causing federal health care programs to pay for false claims submitted in violation of federal law.

126. By reason of Defendants' conspiracy, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each false or fraudulent claim caused to be submitted.

FOURTH CLAIM FOR RELIEF

Violations of Texas Law
TEX. HUM. RES. CODE § 36.002(13)

127. Relator realleges and incorporates by reference each of the preceding paragraphs as if fully set forth in this claim for relief.

128. The TMFPL, among other things, specifies certain "unlawful acts" in Section 36.002 of the Texas Human Resources Code. These unlawful acts include

knowingly engaging in conduct that constitutes a violation under Section 32.039(b) of the Texas Human Resources Code.

129. Through the acts and omissions alleged above, Defendants committed violations of Section 32.039(b) of the Texas Human Resources Code, including violations of Section 32.039(b)(1) and Section 32.039(b)(1-a) through (1-f).

130. Each violation of Section 32.039(b)(1-a) and the Texas Patient Solicitation Act, Texas Occupations Code 102.001, whether or not the unlawful conduct is related to reimbursement by any federal or state health care programs, is subject to penalties under the TMFPL.

PRAYER FOR RELIEF

WHEREFORE, Relator respectfully prays for judgment against Defendants as follows:

a. On Claims for Relief One, Two, and Three (False Claims Act), treble damages and all applicable civil penalties in the maximum amount allowed by law;

b. On Claim Four (Texas Law), double damages and all applicable civil penalties in the maximum amount allowed by law;

c. All attorney's fees and costs associated with prosecuting this civil action, as provided by law;

d. Interest on all amounts owed to the United States, the State of Texas, and/or Relator; and

e. For all other relief the Court deems just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Relator demands a jury trial for all claims and issues so triable.

May 26, 2020

Respectfully submitted,

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